DAIDS
Bethesda, MD USA

POLICY

DAIDS Policy on Storage and Retention of Clinical Research Records

Approval Date: Pending No.: DRAFT

1.0 PURPOSE

To convey the minimal requirements for retaining clinical research records generated from the conduct of Division of AIDS (DAIDS) funded and/or sponsored clinical research and clinical trials.

2.0 SCOPE

The policy applies to clinical research records that are generated, stored and retained at DAIDS funded and/or sponsored clinical research sites as required by applicable regulations, laws, and policies.

3.0 BACKGROUND

There are various regulations, laws and policies that define what documents must be generated, stored and retained during the conduct of DAIDS funded and/or sponsored clinical research and clinical trials. This policy coveys the minimum standards for clinical research record retention for clinical site operations as required by the DHHS and FDA regulations. Because research may be conducted in a variety of U.S. domestic and international settings, and across diverse patient populations, investigators are advised to contact their local IRB/REC or legal counsel at their institution for guidance about the additional requirements of local regulations, laws and institutional policies.

NOTE: This policy does not address the Federal requirements for retention of **funding related research records**, including financial records, supporting documents, statistical records and all other records pertinent to a Health and Human Service Agency award.[1] For information about records retention policies of funding related research records, please refer to the NIH Grants Policy Statement at:

http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm

4.0 DEFINITIONS

Clinical research records: For the purpose of this Policy, clinical research records include documentation and records as defined in this part; all essential and source documents listed in the DAIDS Policy on Essential Documents Appendix 1[2]; and records, in any form (including, but not limited to, written, electronic, magnetic, and

[1] 45 CFR §74.53

[2] http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Regulatory/

optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, and the actions taken.[3]

Completion of a Clinical Trial:

Essential Documents: Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.[4] See listing of documents at DAIDS Policy on Essential Documents Recordkeeping Requirements Appendix 1, No.: DWD POL-RA-03.00A1

IRB Records: The documentation maintained by the institution, or when appropriate, an IRB, of IRB activities, as required by DHHS 45 CFR §46.103(b)(3-5) and §46.115(b).

Research records for the purpose of investigation research misconduct: Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.[5]

Records of research misconduct proceedings: Includes the records that the institution secures for the proceeding, except duplicate records; the documentation of the determination of irrelevant or duplicate records; the inquiry report and final documents produced in the course of preparing that report, including documentation of any decision not to investigate; the investigation report and all records in support of that report, including the recordings or transcriptions on each interview conducted.[6]

Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays,

[3] ICH E6 Sec. 1.22

[4] ICH E6 Sec. 1.23

[5] PHS 42 CRF §93.224

[6] PHS 42 CRF §93.317(a)

subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).[7]

For additional definitions see DAIDS Glossary

5.0 RESPONSIBILITES

The Institution is required to retain records of IRB activities and certain other records frequently held by investigators for at least three [3] years after completion of the research. The institution/IRB may designate responsibility to investigators to retain certain records (e.g., informed consent documents signed by subjects) on behalf of the institution. The institution/IRB must document this designated responsibility in writing and the investigator must retain the records in some form. Investigators should follow the institution's policies and procedures for retaining records. If investigators who have been designated to retain records on behalf of the institution leave that institution, the investigators and the institution should identify the successor responsible for maintaining those institutional records, either at the original institution or wherever the records are relocated.[8]

The Investigator is responsible for documentation of the informed consent of the subjects - either the signed informed consent form or the short form and the written research summary. Records related to conducted research that are typically held by investigators must be retained for at least three years [3] after completion of the research, unless the IRB waived the requirement for informed consent or the requirement for documentation of informed consent.

6.0 POLICY

6.1 Governing Law

Records management requirements established by Federal law are the minimum standard. It is important to note that where record management requirements for DAIDS-funded and/or sponsored clinical research and clinical trials are subject to more than one Federal regulation and, in addition,

[7] ICH E6 Sec. 1.52

[8] http://answers.ohrp.hhs.gov/cgibin/answers_ohrp.cfg/php/enduser/std_adp.php?p_faqid=1548&p_created=1157481814&p_sid=RjiEbgMi&p_accessibility=0&p_lva=&p_sp=cF9zcmNoPTEmcF9zb3J0X2J5PSZwX2dyaWRzb3J0PSZwX3Jvd19jbnQ9MTImcF9wcm9kcz0mcF9jYXRzPTI5MCZwX3B2PSZwX2N2PTEuMjkwJnBfcGFnZT0x&p_li=&p_topview=1

subject to State, local, foreign law, and funding or institutional policies, the requirements of each set of regulations must be considered.

6.1.1 This policy documents the applicable regulatory requirements of the Department of Health and Human Services (DHHS) Federal Policy on Human Subject Protection 45 CFR §46 and Food and Drug Administration Investigational New Drug Application, 21 CFR §312.

6.1.2 All records (e-mail and non-e-mail) pertaining to this policy must be retained and disposed of under the authority of the NIH Manual Chapter 1743, "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule; Section 3000 Intramural Activities, Items G. Research Protocols and H. Clinical Research, including any other sections that apply.

6.1.3 Where DAIDS holds the Investigational New Drug Application and funds the study; that study is subject to <u>both</u> HHS and FDA regulations.

6.1.4 Where institutional policy, U.S. state and/or regional/country specific regulations and/or laws are more protective and/or restrictive than Federal law, DAIDS advises institutions and investigators to consult legal counsel and/or regulatory advisors to determine the records retention requirements. For example, Federal law requires that IRB records be maintained for at least three [3] years after the conclusion of research however, an institutional policy may require that IRB records be maintained for five [5] years. In this example, the institutional policy may govern the retention time requirements.

6.2. <u>Storage</u>

Clinical research records shall be stored in a manner that ensures privacy, confidentiality, security and accessibility of the records both during the conduct of clinical research and clinical trials, and after research/trial is concluded.

6.3 <u>Record Keeping Requirements of Federal Policy for Human Subject Protection</u>

The institution, or when appropriate the investigator, maintain adequate documentation of all clinical research records as defined in Section 4.0 Definitions of this document.

6.3.1 Records may be preserved in hardcopy, electronic or other media form. Retention of multiple copies of each record is not required.

6.3.2 Records must be retained for at least three [3] years after the completion of research.

6.3.3 Records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner.[9]

6.4 Record Keeping Requirements of the Food and Drug Administration (FDA) Federal Policy for Studies Conducted Under an Investigational New Drug (IND) Application

6.4.1 For records that were generated during the conduct of a study under a U.S. FDA IND, an investigator shall retain records required to be maintained under this part for a period of two [2] years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two [2] years after the investigation is discontinued and FDA is notified.[10]

6.3.2 Records required to be maintained under this part are defined in this policy as Essential Documents, Source Documents and clinical research related records (See §4.0 Definitions).

6.4 Special Circumstance

6.4.1 Treatment Use of an Investigational New Drug/HIPAA

If a U.S. domestic institution conducting the research is a covered entity, and the research is being conducted as part of treatment, clinical research related records that are part of the designated record set must be stored, retained and disposed of in accordance with the privacy, confidentiality and security regulations 45 CFR §164 (HIPAA) in addition to FDA and HHS requirements.

Generally, clinical research-related records subject to HIPAA must be retained for six [6] years from the date of creation or the date when the records were last in effect, whichever is later.[11]

[9] 45 CFR §46.115(b)

[10] 21 CFR §312.62(c)

[11] 45 CFR §164.530(j)

Because the record keeping regulations of HIPAA are complex, DAIDS advises institutions and investigators that are part of a covered entity, and that conduct research as part of treatment, to consult their institution's policies and procedures, HIPAA Privacy and Security officials, and legal counsel and/or risk management personnel to determine the records retention requirements under HIPAA.

6.4.2 Children

In general, the record retention rules for the clinical research records of children vary by jurisdiction. Therefore, investigators and clinical research site personnel are advised to review their institutional policy and U.S. state and/or regional/country-specific regulations and/or laws to determine the regulatory requirements related to maintaining clinical research records of children.

6.4.3 Research misconduct

The institution, as the responsible legal entity for DAIDS funded and/or sponsored research, has a continuing obligation to ensure that it maintains adequate records for a research misconduct proceeding.[12] Unless custody has been transferred to HHS, or the Office of Research Integrity has advised the institution in writing that it no longer needs to retain the records, an institution must maintain records of research misconduct proceedings in a secure manner for seven [7] years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation as provided by law, whichever is later.[13]

6.4.4 Collaboration with other Federal department or agencies.

DAIDS may fund and/or sponsor clinical research or clinical trials that involve collaboration with other Federal departments or agencies, sixteen of whom have adopted Federal Policy for the Protection of Human Research Subjects.[14] When collaborating with

[12] PHS 42 CFR §93 Research misconduct

[13] PHS 42 CFR §93.317(b) Maintenance of record

[14] Departments of Agriculture (7 CFR Part 1c), Commerce (15 CFR Part 27), Defense (32 CFR Part 219), Education (34 CFR Part 97), Energy (10 CFR Part 745), Housing and Urban Development (24 CFR Part 60), Justice (28 CFR Part 46), Transportation (49 CFR Part 11), and Veterans Affairs (38 CFR Part 16); National

another Federal department or agency, the record keeping requirements of 45 CFR §46.115 are the minimum standard that must be met, unless the collaborating department or agency has adopted more protective standards.[15]

6.4.5 Tobacco Litigation

As of December 15, 2006, DAIDS, in collaboration with the NIH Office of the General Counsel has determined that only those research-related records, which are HHS property and remain in your possession, should be held. Grantees should seek legal guidance on whether or not their records are subject to any limitations on their destruction.

6.4.6 Records of Closing Sites

In general, each research institution and/or investigator is responsible for retaining study documents for as long as required by regulations, or longer if required by local institution or IRB policy, even if funding has been discontinued and/or the site has been closed.
Upon closure of a research site, the investigator, in collaboration with DAIDS, shall determine which records shall be transferred to DAIDS and/or to an alternative research site, and which records must be stored locally.

7.0 REFERENCES

45 CFR §46.115, *IRB records*
21 CFR §312.62, *General Responsibilities of Investigators*
21 CFR §312.57, *Record Keeping and Record Retention*
45 CFR §164, *Privacy and Security of Protected Health Information (HIPAA)*
Office for Human Research Protections (OHRP) IRB Guidebook
http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

NIH Records Management Officer, Office of Management Assessment (OMA), Office of Administration (OA), Keeping and Destroying Records

Aeronautics and Space Administration (14 CFR Part 1230), Consumer Product Safety Commission (16 CFR Part 1028), and National Science Foundation (45 CFR Part 690); International Development Cooperation-Agency for International Development (22 CFR Part 225), and Environmental Protection (40 CFR Part 26)

[15] http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

http://www1.od.nih.gov/oma/manualchapters/management/1743/)

DAIDS Policy Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials,
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Clinical_Site/

DAIDS Policy Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials,
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Regulatory/

Human Research Questions & Answers, Office for Human Research Protections (OHRP) "What records should investigators keep, and for how long?",
http://answers.ohrp.hhs.gov/cgibin/answers_ohrp.cfg/php/enduser/std_adp.php?p_faqid=1548&p_created=1157481814&p_sid=RjiEbgMi&p_accessibility=0&p_lva=&p_sp=cF9zcmNoPTEmcF9zb3J0X2J5PSZwX2dyaWRzb3J0PSZwX3Jvd19jbnQ9MTImcF9wcm9kcz0mcF9jYXRzPTI5MCZwX3B2PSZwX2N2PTEuMjkwJnBfcGFnZT0x&p_li=&p_topview=1

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at: NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm

10.0 CHANGE SUMMARY

This policy is the first version. It does not supersede any other version.

11.0 APPENDICIES

None

12.0 APPROVAL

/Dr. Richard Hafner, MD/
Richard Hafner